

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
12 August 2004 (12.08.2004)

PCT

(10) International Publication Number
WO 2004/067071 A1

(51) International Patent Classification⁷: **A61M 16/06**

GU14 6QF (GB). **RATHBONE, Thomas** [GB/GB]; 12 Broomleaf Road, Farnham, Surrey GU9 8DG (GB).

(21) International Application Number:
PCT/GB2004/000352

(74) Agents: **WICKHAM, Michael** et al.; The Boc Group Plc, Chertsey Road, Windlesham, Surrey GU20 6HJ (GB).

(22) International Filing Date: 29 January 2004 (29.01.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
0302196.1 30 January 2003 (30.01.2003) GB

(71) Applicant (for all designated States except US): **THE BOC GROUP PLC** [GB/GB]; Chertsey Road, Windlesham, Surrey GU20 6HJ (GB).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

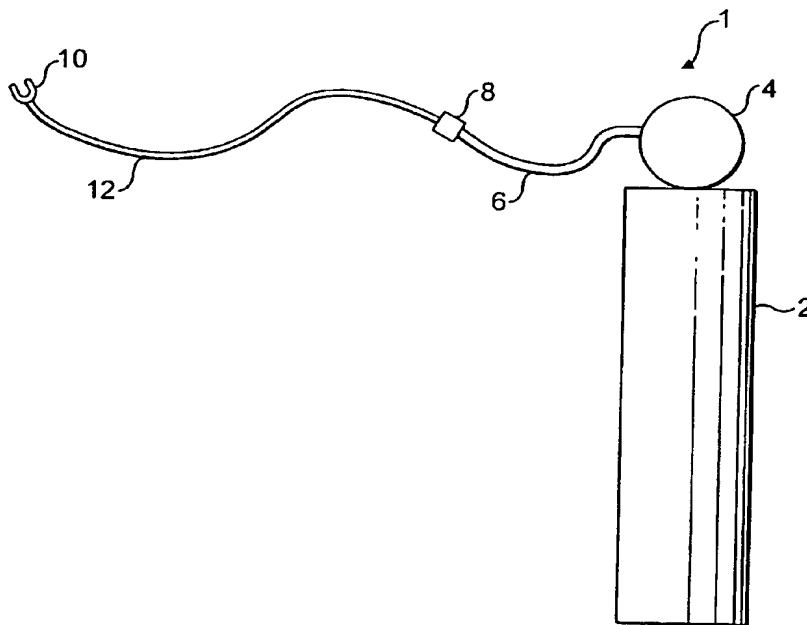
(72) Inventors; and

(75) Inventors/Applicants (for US only): **GARRETT, Michael, Ernest** [GB/GB]; 92 York Road, Woking, Surrey GU22 7XR (GB). **LLOYD, Geoffrey, Morgan** [GB/GB]; Penn Cottage, 17 Church Road West, Farnborough, Hants

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK,

[Continued on next page]

(54) Title: NASAL CANNULA



(57) Abstract: A nasal cannula (1) for inclusion in medical apparatus that delivers a breathable gas mixture of helium and oxygen to a patient comprises a length (12) of high pressure narrow bore tubing having a proximal end region for connection to a high pressure source, a cylinder (2), of the breathable gas mixture at a junction (8). The length (12) of tubing has a distal end region connected to at least one nasal administration device (10). The distal end region of the length (12) of tubing has an orifice for the expansion of the breathable gas mixture.



TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, — *with amended claims*
ML, MR, NE, SN, TD, TG).

Published:

— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

NASAL CANNULA

The present invention relates to medical apparatus and cannula for delivering a breathable gas mixture to a patient.

It is known to administer oxygen to a patient so as to facilitate their breathing.

It is also known to deliver helium/oxygen gas mixtures to a patient with breathing difficulties to reduce airway resistance and improve lung ventilation. Known methods of delivery utilise one or more cylinders of gas. Each cylinder has associated with it a two stage pressure regulator to reduce the pressure of the gas from a high storage pressure (typically in the order of 200 bar) to near atmospheric pressure. The gas flows through relatively wide diameter tubing to an administration device, for example a nasal cannula. The gas is administered to the patient at room temperature. An example of a known nasal cannula for operation of approximately atmospheric pressure is disclosed in GB-A-1 081 807.

It is an aim of the present invention to provide an improved apparatus for delivering a breathable gas mixture including helium to a patient which does not require plural stage gas regulation.

According to the present invention there is provided a nasal cannula for delivering a breathable gas mixture comprising helium and oxygen to a patient, the nasal cannula comprising a length of high pressure narrow bore tubing having a proximal end region for connection to a high pressure source of the breathable gas mixture and a distal end region connected to at least one nasal administration device, wherein the nasal administration device or the distal end region of the tubing has at least one orifice for the expansion of the breathable gas mixture.

The invention also provides apparatus for administering a breathable gas mixture comprising helium and oxygen including means for supplying the breathable gas mixture at a high pressure and a nasal cannula according to the invention.

- 2 -

The nasal cannula and apparatus according to the invention offer the following advantages. First, the requirement for plural stage gas regulation to reduce the supply pressure to near atmospheric pressure is eliminated. Typically, a single stage regulator is used to supply the breathable gas at a pressure in the range of 100 to 300 bar. At such high supply pressures, the cannula tubing need only have a narrow bore. Therefore, unsightly wide bore tubing is avoided.

The breathable gas mixture is preferably a helium-oxygen mixture containing from, say, 20 to 30% by volume of oxygen (and hence 70 to 80% by volume of helium). Every gas has a Joule-Thomson inversion temperature. Above the inversion temperature throttling of the gas through an expansion orifice leads to its heating. Below the inversion temperature such throttling of the gas leads to its cooling. At ambient temperature oxygen is cooled on being expanded, but helium is warmed. The pressure at which the cannula receives the breathable gas and the composition of the mixture may thus be selected to give a desired degree of warming to the gas mixture on expansion through the said orifice. Indeed, an inhaled gas at close to the ideal tracheal temperature of the human body can be formed. Such a temperature facilitates a patient's breathing.

The breathable mixture of helium and oxygen may be stored at the desired high pressure in a gas cylinder.

The high-pressure tubing may be coiled.

The high-pressure tubing may be of a ductile metal or alloy, for example a cupro-nickel alloy.

The high pressure tubing may be surrounded by a protective sheath. The protective sheath may be of plastic material.

The nasal administration device may be a device defining a nasal prong or pair of nasal prongs.

- 3 -

An embodiment of the invention will now be described by way of example, reference being made to the Figures of the accompanying diagrammatic drawings in which:

Figure 1 is a schematic view of an apparatus for delivering a breathable gas mixture under pressure to a patient according to the present invention;

Figures 2a and 2b are schematic details of a coiled high pressure line forming part of the apparatus of Figure 1; and

Figure 3 is a schematic detail of an end of a coiled high pressure line terminating at a tubular nasal prong forming part of the nasal cannula forming part of the apparatus of Figure 1.

As shown in Figure 1, an apparatus 1 for delivering a breathable gas mixture including helium under pressure to a patient comprises a source of the gas mixture in the form of a cylinder 2 to which is mounted a single stage gas regulator 4 in a manner known per se. Preferably, the mixture contains 28% by volume helium, the remainder being oxygen.

A high pressure flexible braided hose 6 extends from the regulator 4 to a junction 8. A nasal cannula 7 is connected at its proximal end to the junction 8. The cannula 7 comprises a coiled high pressure tubing 12 and a nasal gas administration device 10.

Referring also to Figures 2a, 2b the coiled high pressure tubing 12 comprises a coiled high pressure cupro-nickel tube 14 having an internal diameter of between 10 and 15 thousandths of an inch enclosed within a tubular flexible protector sheath 16.

The coiled high pressure tubing 12 terminates at its distal end region in a tubular nasal prong or prongs 18 (see Figure 3) forming part of the nasal cannula 10 where it is formed with an expansion orifice 20. The tubular nasal prong 18 is formed with a

- 4 -

plurality of perforations 22 which allow the flow of the gas mixture from the cannula 10 in to the nasal passages of a patient.

In use, the gas mixture under high pressure leaves the cylinder 2 and passes through the regulator 4. The pressure at the outlet of the regulator 4 is preferably in the range 100 bar to 300 bar. The gas mixture passes via the high pressure flexible braided hose 6 to the cannula 7..

The gas mixture leaves the coiled high pressure tubing 12 of the cannula 7 through the expansion orifice 20 and is thereby expanded from the pressure in the range of 100 bar to 300 bar to a pressure that is approximately atmospheric pressure. The atmospheric pressure gas passes through the perforations 22 for passage in to the nasal cavities of a patient.

A particular advantage of the embodiment described above is that if a mixture of oxygen and helium is expanded the combined Joule Thomson effect of expanding both helium and oxygen is one of heating. The gas is thus raised in temperature by a few degrees Celsius. In the preferred mixture of 28% helium in oxygen the temperature of gas can be raised approximately 14°C above ambient yielding an inhaled gas which is close to the ideal tracheal temperature of the body. Thus the patient is provided with a slightly warmed gas with enhanced oxygen and easy breathability and the pressure of the gas mixture precludes any possibility of blockage by bodily fluids.

As modelled with HYSYS v 3.0.1 software using Peng Robinson with Lee-Kessler mixing rules a 28% by volume oxygen, 72% by volume helium mixture shows the following rise in temperature following an expansion to atmospheric pressure when the mixture is received at 20°C for expansion.

Upstream pressure (Bar)	300	200	100
Joule Thomson temperature rise (K)	13.6	8.3	3.6

- 5 -

CLAIMS

1. A nasal cannula for delivering a breathable gas mixture comprising helium and oxygen to a patient, the nasal cannula comprising a length of high pressure narrow bore tubing having a proximal end region for connection to a high pressure source of the pressure breathable gas mixture and a distal end region connected to at least one nasal administration device, wherein the nasal administration device or the distal end region of the tubing has at least one orifice for the expansion of the breathable gas mixture.
2. A nasal cannula according to claim 1, wherein the high pressure narrow bore tubing is coiled.
3. A nasal cannula according to claim 1 or claim 2, wherein the high pressure narrow bore tubing is of a ductile metal or alloy.
4. A nasal cannula according to claim 3, wherein the alloy is a cupro-nickel alloy.
5. A nasal cannula according to any one of the preceding claims, wherein the high pressure narrow bore tubing is surrounded by a protective sheath.
6. A nasal cannula according to any one of the preceding claims, in which the nasal administration device defines a nasal prong or a pair of nasal prongs.
7. Apparatus for administering a breathable gas mixture comprising helium and oxygen including means for supplying the breathable gas mixture at a high pressure and a nasal cannula according to any one of claims 1 to 6.
8. Apparatus according to claim 7, wherein the said means includes a gas cylinder in which the breathable gas mixture is stored under pressure.

- 6 -

9. Apparatus according to claim 8, wherein the stored breathable gas mixture contains from 70 to 80% by volume of helium and from 20 to 30% by volume of oxygen.
10. Apparatus according to claim 8 or claim 9, wherein the stored breathable gas mixture is stored in the cylinder at a pressure in the range of 100 bar to 300 bar.
11. Apparatus according to any one of claims 8 to 10, wherein the stored breathable gas mixture contains 72% by volume of helium, balance oxygen.

AMENDED CLAIMS

**[Received by the International Bureau on 07 June 2004 (07.07.2004);
original claim 1 replaced by amended claim 1; other claims remain unchanged
(1 page)]**

1. **A nasal cannula for delivering a breathable gas mixture comprising helium and oxygen to a patient, the nasal cannula comprising a length of high pressure narrow bore tubing having a proximal end region for connection to a high pressure source of the breathable gas mixture at a pressure in the range of 100 bar to 300 bar and a distal end region connected to at least one nasal administration device, wherein the nasal administration device or the distal end region of the tubing has at least one orifice for the expansion of the breathable gas mixture.**
2. **A nasal cannula according to claim 1, wherein the high pressure narrow bore tubing is coiled.**
3. **A nasal cannula according to claim 1 or claim 2, wherein the high pressure narrow bore tubing is of a ductile metal or alloy.**
4. **A nasal cannula according to claim 3, wherein the alloy is a cupro-nickel alloy.**
5. **A nasal cannula according to any one of the preceding claims, wherein the high pressure narrow bore tubing is surrounded by a protective sheath.**
6. **A nasal cannula according to any one of the preceding claims, in which the nasal administration device defines a nasal prong or a pair of nasal prongs.**
7. **Apparatus for administering a breathable gas mixture comprising helium and oxygen including means for supplying the breathable gas mixture at a high pressure and a nasal cannula according to any one of claims 1 to 6.**
8. **Apparatus according to claim 7, wherein the said means includes a gas cylinder in which the breathable gas mixture is stored under pressure.**

1 / 2

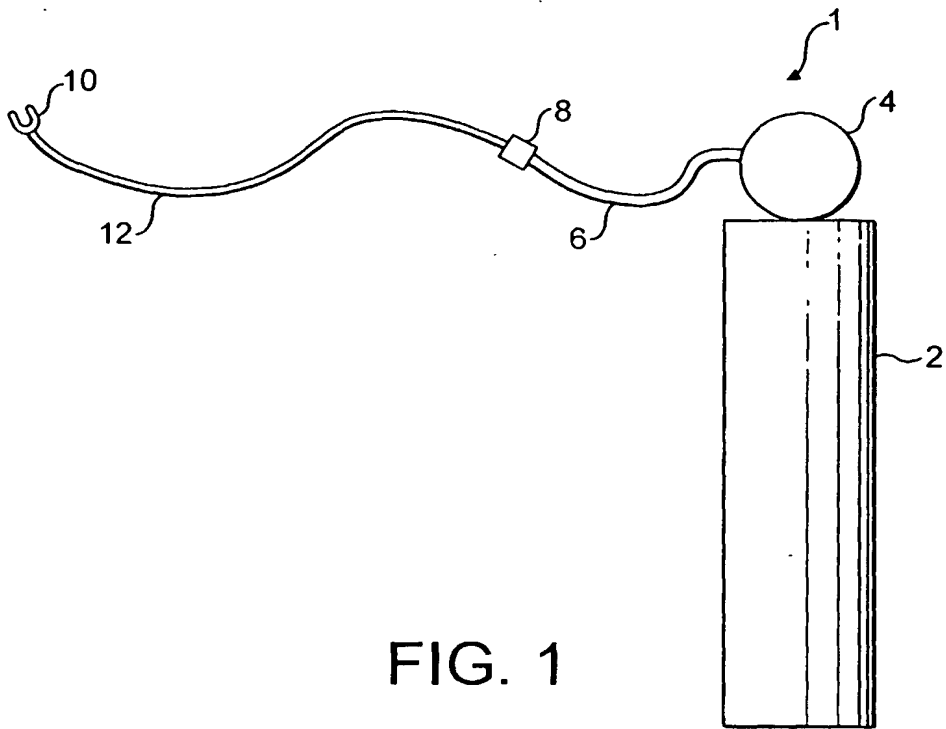


FIG. 1

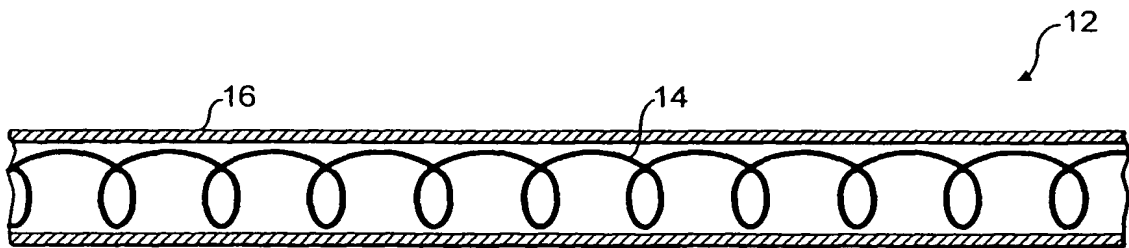


FIG. 2a

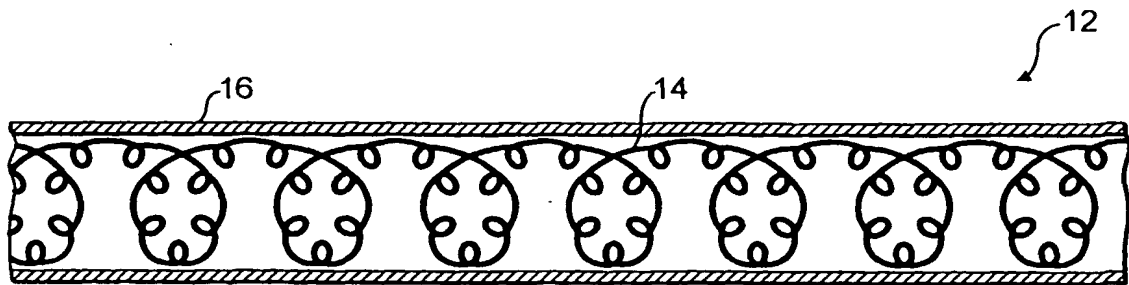


FIG. 2b

2 / 2

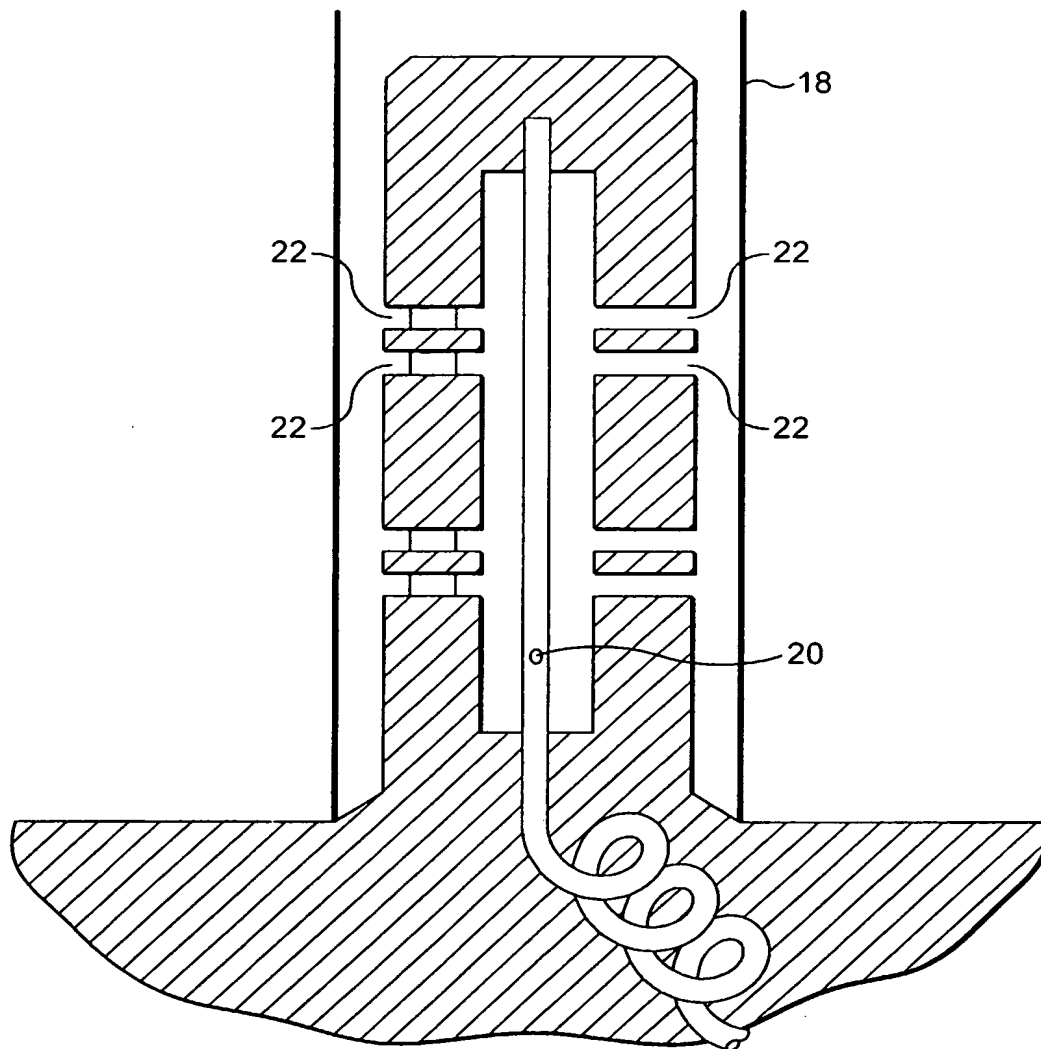


FIG. 3

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB2004/000352

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M16/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 535 767 A (PHILLIPS ROBERT E ET AL) 20 August 1985 (1985-08-20) column 3, line 18 -column 4, line 8; figure 4	1,5-7
X	WO 99/24101 A (KNI EWASSER GERT; MED IN MEDICAL INNOVATIONS (DE); WERNER LISELOTTE) 20 May 1999 (1999-05-20) page 10, line 1 -page 15, line 18; figure 1	1,6,7
A,P	EP 1 334 741 A (WEINMANN G GERAETE MED) 13 August 2003 (2003-08-13) column 8, line 40 -column 9, line 41; figure 7	1,2,6-8, 10

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *G* document member of the same patent family

Date of the actual completion of the international search

27 Apr11 2004

Date of mailing of the international search report

07/05/2004

Name and mailing address of the ISA
European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Kroeders, M

INTERNATIONAL SEARCH REPORT

In
national Application No
PCT/GB2004/000352

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 4535767	A	20-08-1985	AU 2120483 A	24-04-1984
			AU 2124483 A	24-04-1984
			DE 3390236 T	29-11-1984
			DK 269984 A	30-05-1984
			EP 0120926 A1	10-10-1984
			EP 0120941 A1	10-10-1984
			GB 2142545 A ,B	23-01-1985
			NL 8320328 T	01-08-1984
			SE 8402954 A	30-05-1984
			WO 8401293 A1	12-04-1984
			WO 8401295 A1	12-04-1984
<hr/>				
WO 9924101	A	20-05-1999	DE 29719834 U1	08-01-1998
			AU 6498498 A	31-05-1999
			WO 9924101 A1	20-05-1999
			EP 0961626 A1	08-12-1999
<hr/>				
EP 1334741	A	13-08-2003	DE 10205955 A1	21-08-2003
			EP 1334741 A1	13-08-2003
<hr/>				